

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To

PCT

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or Agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No
PCT/GB2004/000789

International filing date (day/month/year)
27.02.2004

Priority date (day/month/year)
22.04.2003

International Patent Classification (IPC) or both national classification and IPC
A61M15/00, G01F11/16, G01F11/02

Applicant
BESPAK PLC

1 This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2 FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3 For further details, see notes to Form PCT/ISA/220

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WRITTEN OPINION OF THE
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International application No
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Box No. 1 Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language . which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b))
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments.

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Box No. II Priority

1 ☒ The following document has not been furnished

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b))

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2 ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 10-17

because:

- ☒ the said international application, or the said claims Nos. 10-17, relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos., are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 10-17
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

WRITTEN OPINION OF THE
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International application No
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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2-6
	No: Claims	1, 7, 8, 9
Inventive step (IS)	Yes: Claims	2-6
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-9
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted.

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- 1 Method claims 10 to 15 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. In fact, independent method claim 10 is applied in order to **expel medicament** from the metering tube (see step (d) of method claim 10). This step of **"expelling medicament from said metering tube"** represents at least a step of medical treatment by therapy.
Therefore, method claims 10 to 15 are considered as methods for the treatment of the human body by therapy. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).
- 2 Claims 16 and 17 rely, in respect of the technical features of the invention, on references to the description or drawings. However, Rule 6.2 (a) PCT clearly specifies that claims shall not rely on such references as "as described herein with reference to the attached Figures" (cf. claims 16 and 17). Consequently, no opinion will be formulated with respect to these claims.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

3. Reference is made to the following documents:
D1: WO-A-02/26299 (SCHUCKMANN ALFRED VON) 4 April 2002
D2: US-A-4 394 941 (RECINE GIUSEPPE) 26 July 1983
D3: US-A-3 049 269 (ALAN GAWTHROP) 14 August 1962
D4: US-A-1 233 791 (KAISER CHARLES)

..... **lack of novelty**

4. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claim 1 is not new in the sense of Article 33(2) PCT. The document **D1** discloses (the references in parentheses applying to this

document) a dispensing apparatus (fig.1) comprising:

- a housing ("Gehäuse 3") and a metering tube ("Röhrchen 22"), said metering tube ("Röhrchen 22") having an opening (at the top thereof) to the interior thereof and said housing ("Gehäuse 3") having a chamber ("Vorratskammer 2") therein for storing medicament ("Pulver");
- said metering tube ("Röhrchen 22") being extendable to a dispensing position ("Ausgabebereitschaftsstellung" - fig.5), and retractable to a filling position (fig.1);
- wherein said opening (top of the metering tube) is in communication with said chamber ("Vorratskammer 2") when said metering tube ("Röhrchen 22") is in said filling position (fig.1).

The subject-matter of independent claim 1 is therefore not new (Article 33(2) PCT).

5. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claim 1 is also not new (Article 33(2) PCT) with regard to the disclosure of documents D2 to D4. In fact:

- (A) The document D2 discloses (the references in parentheses applying to this document) a dispensing apparatus ("dispenser 10" shown in figures 1-5) comprising:
- a housing ("container 22") and a metering tube ("cylindrically shaped member 32"), said metering tube ("cylindrically shaped member 32") having an opening ("opening 40") to the interior thereof and said housing ("container 22") having a chamber ("upper portion 24" of the "container 22") therein **suitable for** storing medicament ("liquids");
 - said metering tube ("cylindrically shaped member 32") being extendable to a dispensing position (fig.5), and retractable to a filling position ("fill position" - fig.3);
 - wherein said opening ("opening 40") is in communication with said chamber ("upper portion 24") when said metering tube ("cylindrically shaped member 32") is in said filling position ("fill position" - fig.3).
- (B) The document D3 discloses (the references in parentheses applying to this document) a dispensing apparatus (fig.1) comprising:
- a housing ("container" - c.2, l.56) having a chamber (interior of "member 11") therein;
 - a metering tube ("tube 1") having an opening ("orifice 5") to the interior thereof, said

metering tube being extendable to a dispensing position ("outermost position" - fig. 1), and retractable to a filling position ("depressed position" - see also c.3. I.1 to I.17):

- (C) The document **D4** discloses (the references in parentheses applying to this document) a dispensing apparatus (fig.1-3) comprising:
- a housing ("tank 5") having a chamber (interior of "tank 5") therein;
 - a metering tube ("cylinder 9") having an opening ("opening 10") to the interior thereof, said metering tube being extendable to a dispensing position (fig.3), and retractable to a filling position (fig.2);

The subject-matter of independent claim 1 is therefore not new (Article 33(2) PCT).

6. The additional features of dependent claims 7 to 9 are already known from D1 so that these claims also lack novelty (Article 33(2) PCT).
- **Claim 7:** the stop ("Mitnehmervorsprünge 47") is provided to limit the displacement of the metering tube ("Röhrchen 22").
 - **Claim 8:** the dispensing apparatus is provided in a hand-held inhaler ("Inhalator") for oral delivery ("Mundstück 10") of medicament ("Medikamentenpulver").
 - **Claim 9:** the medicament ("Medikamentenpulver") is delivered as an atomised mist (see fig 6).

----- positive assessment -----

7. The combination of the features of dependent claim 2 is neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:

The document **D2** is regarded as being the closest prior art to the subject-matter of claim 2, and discloses a dispensing apparatus (see paragraph 5(A) of the present written opinion) having a piston ("plunger 44") used for moving the metering tube ("cylindrical member 32") from the filling position to the dispensing position. Hence, the subject-matter of claim 2 differs from this known apparatus in that the piston is suitable **"for drawing medicament into said metering tube and expelling medicament from said metering tube"**. The problem to be solved by the present invention may therefore be regarded as **"how to provide an alternative solution for the manual delivery of the medicament"**.

None of the cited documents discloses or renders obvious the solution proposed in dependent claim 2 (the solution consisting in a piston for drawing medicament into the extendable/retractable metering tube and expelling medicament from the extendable/retractable metering tube): the fluid dispenser of D2 would required to many modifications in order to arrive at a dispensing apparatus according to claim 2. Consequently, the subject-matter of dependent claim 2 is new (Article 33(2) PCT) and inventive (Article 33(3) PCT).

- 7.1 Dependent claims 3 to 6 define preferred embodiments of the dispensing apparatus of claim 2. Therefore, the subject-matter of dependent claims 3 to 6 is also new (Article 33(2) PCT) and inventive (Article 33(3) PCT).

----- industrial applicability -----

8. The subject-matter of claims 1 to 9 is considered as industrially applicable (Article 33(4) PCT) since it can be made or used in any kind of industry.
- 8.1 Consequently, the subject-matter of claims 2 to 6 fulfills the requirements of patentability set out in Articles 33(1)-(4) PCT.

Re Item VII

Certain defects in the international application (form and content)

9. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 to D4 is not mentioned in the description, nor are these documents identified therein.
10. The independent claim should have been written in the two-part form in accordance with Rule 6.3(b) PCT with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
11. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

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